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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,974	11/30/2001	Daniela Salvemini	MPI 8313.3	5898

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EXAMINER

FONDA, KATHLEEN KAHLER

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 12/06/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/997,974

Applicant(s)

SALVEMINI, DANIELA

Examiner

Kathleen Kahler Fonda, Ph.D.

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-- The MAILING DATE of this communication appears n th c ver sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other: _____

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The Examiner recognizes that Applicant has asserted a claim of benefit to application number 09/634,152, now U.S. Patent 6,395,725. The instant case is a continuation-in-part of that application. However, Applicant is not entitled to the claimed benefit because 09/634,152 does not provide support for the invention now claimed.

Claims 1, 4, and 8 are objected to because of the following informalities: None of these claims ends with a period. Appropriate correction is required.

Applicant is advised that should claim 8 be found allowable, claims 9 and 10 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claims 9 and 10 merely recite an intended use for the composition of claim 8, and thus are not further limiting.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-6, and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by SALVEMINI et al. (45). SALVEMINI teaches administration of a pharmaceutical composition comprising 1 to 10 mg/kg of M40403 to a rat, for treatment of inflammation. M40403 is the pentaaza-macrocyclic ligand complex of the claims. See the first paragraph in the right column on page 304, and Figure 1. As for claims 4 and 5, the Examiner notes that there is no requirement that the subject be afflicted with arthritis or rheumatoid arthritis at the time of the administration. Thus the claims are anticipated.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over SALVEMINI *et al.* (45).

Applicant claims a method of treating an inflammatory disease which may be arthritis, in a subject which may be a human, by administering a pentaaza-macrocyclic ligand complex as recited in the claims.

SALVEMANI teaches as set forth above. SALVEMINI does not specifically disclose administration to a human.

It would have been obvious for a person of ordinary skill in the art at the time of the invention to administer compound M40403 to a human. An ordinarily skilled worker would have been motivated to do so, with a reasonable expectation of success, because SALVEMINI teaches that "inflammatory processes, such as arthritis" are oxidative stress-related diseases (left column, page 304). SALVEMINI also states that "the biological properties of M40403 mimic those of the native enzymes that have been shown to attenuate edema" (right column, page 304). Furthermore, SALVEMINI specifically suggests the potential of M40403 for treatment of diseases such as "acute and chronic

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inflammation" (left column, page 306). Thus the claims are obvious.

No claim is allowed.

As to the Information Disclosure Statement filed on 04-11-02, Applicant is advised that although references 53 and 57 have been considered, these references cannot be listed on any patent which may issue from this application unless Applicant provides at least the year of publication.

Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The number of the fax machine for official papers in Technology Center 1600 is (703) 308-4556. Any document submitted by facsimile transmission will be considered an official communication unless the cover sheet clearly indicates that it is an informal communication.

INTERNET INFORMATION: Secure and confidential access to patent application status information is now available; see <http://www.uspto.gov/ebc/index.html> for more information. Also, <http://www.uspto.gov/web/offices/ac/comp/fin/clonedefault.htm>

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may be used to pay patent maintenance fees, pay non-filing application fees, and maintain USPTO deposit accounts.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Kathleen Kahler Fonda, at telephone number (703) 308-1620. Examiner Fonda can generally be reached Monday through Friday from 7:30 a.m. until 4:00 p.m. If the Examiner cannot be reached, questions may be addressed to Supervisory Patent Examiner James O. Wilson at (703) 308-4624. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.



Kathleen Kahler Fonda, Ph.D., J.D.
Primary Examiner
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